HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097

December 16, 1999

WARNING LETTER
CIN-WL-00-2-0

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

S. Michael Forsythe, DVM, Owner
Amanda Animal Hospital
6550 Lancaster-Circleville Rd.
Lancaster, OH 43130

Dear Dr. Forsythe:

During an investigation at the James R. Cooksey farm, Circleville, Ohio, it was determined that you provide their veterinary services. Our investigation documented that you treated a beef steer belonging to [redacted] for a sore (lame) foot, on June 7, 1999. The treatment consisted of administration of a single 4-5 gram dose of an oral phenylbutazone paste. You advised the clients that the withdrawal period was either 10 or 14 days. This animal was subsequently sold for slaughter at the [redacted], on 6/26/99. The animal was subsequently slaughtered, on 6/28/99. A urine sample was collected from this steer, on 6/24/99, 17 days after the animal was dosed with phenylbutazone. Analysis of this sample indicated a phenylbutazone level greater than 500 ppb (parts per billion) in the urine. These levels yield a calculated level of 72 to 180 ppb in the edible tissue (muscle), a level evaluated and determined to be of significant human health concern. Your extra-label use of this drug has resulted in drug residues in edible tissue, which cause this food animal to be adulterated under section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act).

In October of 1994, Congress passed the Animal Medicinal Drug Use Clarification Act (AMDUCA), which permits extra-label drug use under certain controlled conditions, specified in 21 CFR Part 530. Since phenylbutazone is not approved for use in food producing animals, your administration of the drug to this steer constitutes Extra-Label Drug Use and causes you to be subject to the regulations specified in 21 CFR Part 530.

Our investigation determined that you failed to comply with the requirements for maintaining veterinary records (21 CFR 530.5); and failed to establishing conditions and controls to assure that no illegal drug residues will occur in food-producing animals (21 CFR 530.20). The FDA Investigator issued you an FDA-483, on 8/19/99, which summarized these deviations. These include: (1) Phenylbutazone paste was administered to a steer as an extra-label use, which resulted in an unsafe residue in edible meat that may represent a risk to human health.; (2) failure to take appropriate measures to assure that the 14 day timeframe assigned for withdrawal prior to marketing of meat was supported by appropriate scientific information and would assure no illegal drug residues occur in food-producing animals; and (3) failure to establish adequate records of extralabel drug use that include the condition being treated, the dose administered, the duration of treatment, and the specified withdrawal period or date.

This failure to comply with the regulations specified in 21 CFR Part 530 is a prohibited act under section 301(u) of the Act. This also causes these Extralabel Use Drugs to be adulterated under section 512(a)(1)(A), in that they are not approved for their intended use and they are not exempted under section 512(a)(4) unless you are in compliance with these regulations.

We acknowledge receipt of your September 1, 1999 response to the August 1999 inspectional observations. We find your response to adequate with exception of your Extralabel Drug Use Records. Neither the attached form provided nor your written response letter specifies all of the required information that will be entered into these records, including: condition treated, dosage and method of administration, duration of treatment, and number of animals treated. Please provide verification that procedures are in place to assure these records will be maintained. As you indicated in your letter a copy of this information should be provided to your client, at the time the drug is dispensed or administered, to assure the safe and proper use of the drugs.

You should respond to this office within fifteen (15) working days of receipt of this letter of the additional steps taken to correct these violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. You reply should be sent to Charles S. Price, Compliance Officer, at the above address. If you have any questions, you may call Mr. Price at (513) 679-2700 extension 165.

Sincerely,

Charles W. Sedgwick,
Acting Director,
Cincinnati District Office